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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,564	05/26/2006	Matthias Austen	2923-757	1482

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EXAMINER	
SINGH, ANOOP KUMAR	

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
06/24/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/580,564	AUSTEN ET AL.	
	Examiner	Art Unit	
	Anoop Singh	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-57* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendments to claims filed 5/26/2006 have been received and entered. Claims 4-5, 9-10, 13, 15, 17-22, 28-34, 37, 39-49 have been amended. Claims 1-57 are pending in this application.

Claim Interpretation: Claims 1-25, 53-57 are directed to "uses". These claims are indefinite since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. Additionally, because these claims to set forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim. For the sake of compact prosecution, the Examiner has interpreted claims 1-25, 53-57 to be methods of using product of the invention for its intended effect. If Applicants do not wish for these claims to be interpreted as methods of using the product DG-119-1 and or DG119-2, Applicants are invited to amend the claims, at which point, the Examiner will determine if the amended claims fall within the elected group.

Claims 1-57 are under consideration.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-8, 10-17, 20-25, 35-36,drawn to a method of using to DG119-1 product and/or a DG119-1 agonist and/or of a DG119-2 antagonist for the manufacture of a medicament to stimulate and/or induce the differentiation or development of insulin producing cells from progenitor cells that is administered to

a patient as a pharmaceutical composition directly to the pancreas (protein therapy).

Group II, claims 1-14, 18-25, 35, 38, drawn to a method of using to DG119-1 product and/or a DG119-1 agonist and/or of a DG119-2 antagonist for the manufacture of a medicament to stimulate and/or induce the differentiation or development of insulin producing cells from progenitor cells that is administered to a patient via implantation of active ingredient expressing cells (cell therapy).

Group III, claims 1-14, 18-25, 35, 37, drawn to drawn to a method of using to DG119-1 product and/or a DG119-1 agonist and/or of a DG119-2 antagonist for the manufacture of a medicament to stimulate and/or induce the differentiation or development of insulin producing cells from progenitor cells that is administered to a patient via gene therapy.

Group IV, claims 26-34, 53-57 drawn to a method for differentiating into functional pancreatic cells by cultivating cells capable of being differentiated into pancreatic cells in the presence of an effective amount of a DG119-1 product and/or a DG119-1 agonist and/or a DG119-2 antagonist in vitro (b) allowing the cells to develop, to differentiate at least one pancreatic function.

Group V, claims 39-49, drawn to a cell preparation comprising functional pancreatic cells treated with an active ingredient selected from a DG119-1 product and/or a DG119-1 agonist and/or a DG119-2 antagonist obtainable by the method of claim 26.

Group VI, claims 50-52, drawn to a method for identifying and/or characterizing compounds capable of modulating the differentiation or regeneration of cells into functional pancreatic, particularly insulin-producing cells.

This application contains claims 1, 26, 35, 39, 50, 52, 53, 56 and 57 are directed to more than one DG119-1 product and/or a DG119-1 agonist and/or of a DG119-2 antagonist of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: DG119-1 -1 product and/or a DG119-1 agonist and/or of a DG119-2 antagonist that is either protein or nucleic acid encoding protein.

Applicant is required, in reply to this action, to elect a single DG119-1 product or one specific combination of product to which the claims shall be restricted. The reply must also identify the claims readable on the elected product, including any claims subsequently added.

This is a restriction requirement and not election of species.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A) The invention has no special technical feature that defined the contribution over the prior art, or B) Unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

1) A product and a special process of manufacture of said product.
2) A product and a process of use of said product.
3) A product, a special process of manufacture of said product, and a process of use of said product.
4) A process and an apparatus specially designed to carry out said process.
5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850.

Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention.

The technical feature linking group I-VI is novel DG119-1 and/or agonist and/or DG-119-2 antagonist for using for the manufacture of medicament. Given broadest reasonable interpretation in view of disclosure in the specification, instant claims embrace fragments, homologues or variant of DG-119-1 protein or nucleic acid encoding DG-119-1. It is noted that NCBI accession no AL050137 and AB43286 disclose a homology with DG-119 meeting the limitation of claimed product. Therefore, the instant technical feature does not contribute over prior art.

In addition, the inventions are distinct, each from other because of the following reasons: Inventions I-VI are unrelated. Inventions are unrelated if it can

be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and require different composition, which provide different mode of operation and require distinct, non-coextensive considerations. In the instant case, protein therapy by delivering protein are independent and structurally different as compared to delivering cells expressing protein or a construct comprising gene encoding DG-119-1.. The protein is distinct from cell and nucleic acid because they are structurally different and require distinct method steps to practice. Similarly, a method involving preparing a cell preparation is different from a screening or treatment. Each of these involves distinct and different method steps and composition and therefore, searching for distinct method steps and composition will not be coextensive and will require separate and independent searches in the patent and non-patent literature.

Each invention is directed to distinct goal, which comprises the use bacterium, virus or cell in order to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

Election of species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: cells are selected from embryonic stem cells, adult stem cells, somatic stem cells or progenitor cells.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The

reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
The following claim is generic: claim 26.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: In the instant case the stem cells of each disclosed species type do not share a common structure feature in common with respect to their structure, function and mode of action. Thus, requirement of unity of invention is not fulfilled.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must

require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly

admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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